

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.**

I. PREAMBLE

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, OMJPI is entering into a Settlement Agreement with the United States. OMJPI will also enter into settlement agreements with various States (Related State Settlement Agreements) and OMJPI's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), OMJPI established a voluntary compliance program applicable to all OMJPI employees (Compliance Program). OMJPI's Compliance Program includes a Compliance Officer and a Compliance Committee. The Compliance Program also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, screening measures for Ineligible Persons, and regular internal auditing procedures.

OMJPI shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. OMJPI may modify its Compliance Program as appropriate, but, at a minimum, OMJPI shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by OMJPI under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) OMJPI’s final Annual Report; or (2) any additional materials submitted by OMJPI pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and employees of OMJPI;

b. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of OMJPI; and

c. all employees, contractors, subcontractors, agents and other persons who are members of the Johnson & Johnson North America Pharmaceutical Group’s Health Care Compliance (HCC) team who provide compliance-related support for OMJPI.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.
3. “Government Reimbursed Products” refers to all products of OMJPI that are promoted or sold by OMJPI in the United States that are reimbursed by Federal health care programs.
4. The term “Promotional and Product Services Related Functions” includes: (a) the promotion, marketing, advertising, and sale of Government Reimbursed Products; (b) the development, preparation, or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products; and (c) post-marketing research, development, and publication related-activities involving Government Reimbursed Products.
5. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by OMJPI, including but not limited to, sponsorship of symposia at medical conferences.
6. The term “Third Party Personnel” shall mean personnel of the entities with whom OMJPI has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. OMJPI has represented that: (1) Third Party Personnel are employed by entities independent of OMJPI; (2) OMJPI does not control the Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. OMJPI agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.8 and V.B.5. Provided that OMJPI complies with the requirements of Sections III.B.2, V.A.8 and V.B.5, OMJPI shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

OMJPI shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Certain OMJPI Employees and the Board of Directors.

1. *Compliance Officer.* Prior to the Effective Date, OMJPI appointed a Compliance Officer, and OMJPI shall maintain a Compliance Officer during the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of OMJPI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of OMJPI, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the Chief Legal Officer for OMJPI or Chief Financial Officer for OMJPI. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by OMJPI as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

OMJPI shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after the change.

2. *Compliance Committee.* Prior to the Effective Date, OMJPI established a Compliance Committee, and OMJPI shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, medical affairs/information, sales, marketing, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in

the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

OMJPI shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board shall, at a minimum, be responsible for the following:

- a. The Board shall meet at least quarterly to review and oversee OMJPI's Compliance Program, including but not limited to the performance of the Compliance Officer and compliance personnel who are "Covered Persons" under this CIA.
- b. The Board shall arrange for the performance of a review on the effectiveness of OMJPI's Compliance Program (Compliance Program Review) by the Compliance Expert (described below) for each Reporting Period of the CIA. The Board shall review the Compliance Program Review Report (described below) as part of the review and assessment of OMJPI's Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by OMJPI.
- c. The Board shall retain an independent individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert). The Compliance Expert shall create a work plan for the Compliance Program Review, oversee the performance of the Compliance Program Review, and prepare a written report about the Compliance Program Review and the results of the review. The written report (Compliance Program Review Report) shall include a description of the review and shall include recommendations with respect to the Compliance Program.

d. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of OMJPI's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of OMJPI's Compliance Program, including the performance of the Compliance Officer and the compliance personnel who are “Covered Persons” under this CIA. In addition, the Board has retained a Compliance Expert with expertise in compliance with the Federal health care program and FDA requirements to support the Board's responsibilities. The Board also has arranged for the performance of, and reviewed the results of, the Compliance Program Review, including the Compliance Program Review Report. Based on all of these steps, the Board has concluded that, to the best of its knowledge, OMJPI has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at OMJPI.

OMJPI shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain OMJPI officers or employees (“Certifying Employees”) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable OMJPI business unit is compliant with applicable Federal health care program and FDA requirements, and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the President of OMJPI; Vice-President of Human Resources; Vice-President of Strategic Customer Group; Vice-President of Commercial Analytics; Vice-President of Medical Affairs; Vice President of Communication and Public Policy; Vice-President of New Business Development; General Manager-CNS,

General Manager-IM/Pain; General Manager-Virology; General Manager-Immunology/Oncology; Chief Scientific Officer; Treasurer; and, to the extent that an OMJPI business unit performs sales, marketing, promotion, pricing, contracting, regulatory affairs, compliance, and medical affairs functions is not covered by the certifications of one of the above-listed individuals, such other appropriate OMJPI executives, vice presidents, directors as would be necessary to ensure that there is a certifying officer or employee covering each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of OMJPI is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, OMJPI developed, implemented, and distributed a written Code of Conduct to all Covered Persons. OMJPI has made, and shall continue to make, the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. OMJPI’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;
- b. OMJPI’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with OMJPI’s own Policies and Procedures;

c. the requirement that all of OMJPI's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by OMJPI, suspected violations of any Federal health care program or FDA requirements or of OMJPI's own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and OMJPI's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by OMJPI's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

OMJPI shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, OMJPI shall send a letter to each entity employing Third Party Personnel. The letter shall outline OMJPI's obligations under the CIA and its commitment to full compliance with all Federal health care programs and FDA requirements. The letter shall include a description of OMJPI's Compliance Program. OMJPI shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of OMJPI's Code of Conduct and a description of OMJPI's Compliance Program available to its Third Party Personnel; or (b) represent to OMJPI that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, OMJPI implemented written Policies and Procedures regarding the operation of the Compliance Program and OMJPI's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 120 days after the Effective Date, OMJPI shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. § 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements;
- d. the materials and information that may be distributed by OMJPI sales representatives about OMJPI products and the manner in which OMJPI sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of OMJPI's products;
- e. the materials and information that may be distributed by OMJPI's Medical Affairs and the Medical Information & Services department (collectively hereinafter "Medical Information & Services") and the mechanisms through, and manner in which, OMJPI's Medical Information & Services department receives and responds to requests for information about non-FDA approved (or "off-label") uses of OMJPI's products; the form and content of information disseminated by OMJPI in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that OMJPI develop a database to track requests for information about OMJPI's products that are made to OMJPI's Medical Information & Services department. This database shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about OMJPI's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from OMJPI (including a record of the materials provided to the HCP or HCI in response to the request); and 7) the name of the OMJPI representative who called on or interacted with the HCP or HCI. In addition, HCC will record the date and name of the individual at HCC who reviewed the Inquiry, if applicable.

- f. systems, processes, policies, and procedures relating to the development of call plans for sales representatives who promote Government Reimbursed Products. For each product, the Policies and Procedures shall require that OMJPI review the call plans for the product and the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that OMJPI modify the call plans as necessary in a manner designed to ensure that OMJPI is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;
- g. systems, processes, policies, and procedures relating to the development, implementation, and review of plans for the

distribution of samples by OMJPI of Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from OMJPI (including, separately, from OMJPI sales representatives and OMJPI's Medical Information & Services department). The Policies and Procedures shall also require that OMJPI modify the Sample Distribution Plans as necessary to ensure that OMJPI is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements;

- h. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker training programs, advisory boards, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- i. programs to educate sales representatives, including mentorships. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- j. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that OMJPI's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

- k. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that OMJPI's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) OMJPI disclose its financial support of the Third Party Educational Activity and any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose OMJPI's financial support of the Third Party Educational Activity and any financial relationships that OMJPI might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with OMJPI; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of OMJPI control; 6) OMJPI support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) OMJPI support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- l. review of all promotional and other materials and information intended to be disseminated outside OMJPI by appropriate qualified personnel (such as legal, medical, and/or regulatory personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during OMJPI's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;
- m. sponsorship, funding of, and disclosures relating to research and development-related activities (including clinical trials, market research, or authorship of articles or other publications.) These

Policies and Procedures shall be designed to ensure that OMJPI's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

- n. compensation (including salaries and bonuses) for Relevant Covered Persons who are sales representatives. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of OMJPI's products; and
- o. disciplinary policies and procedures for violations of OMJPI's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), OMJPI shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, OMJPI shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain OMJPI's:

- a. CIA requirements; and
- b. OMJPI's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;
- c. all OMJPI Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional and Product Services Related Functions.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An OMJPI employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to

the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements.

5. *Update of Training.* OMJPI shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

6. *Computer-based Training.* OMJPI may provide the training required under this CIA through appropriate computer-based training approaches. If OMJPI chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. In addition, if OMJPI chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of “hours” of training in this section III.C may be met with respect to computer-based training by providing the required number of “normative” hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, OMJPI shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist OMJPI in assessing and evaluating its Promotional and Product Services Related Functions. More specifically, the IRO(s) shall conduct reviews that assess OMJPI’s systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by OMJPI shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with OMJPI, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

- b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess OMJPI’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in OMJPI’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If OMJPI materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to Inquiries included in OMJPI's Inquiries Database, a review of OMJPI's Call Plan Assessments, a review of Sampling Events, and a review of records relating to a sample of the Payments that are reported by OMJPI pursuant to Section III.L below. In addition, each Transactions Review shall also include a review of up to three additional areas or practices of OMJPI identified by the OIG in its discretion (hereafter "Additional Items".)

For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with OMJPI and may consider internal audit work conducted by OMJPI, OMJPI's product portfolio, the nature and scope of OMJPI's promotional practices and arrangements with HCPs and HCIs, and other information known to it. The OIG shall notify OMJPI of the nature and scope of the IRO Review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or OMJPI shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

- c. *Retention of Records.* The IRO and OMJPI shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and OMJPI) related to the reviews.

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each IRO Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or

Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). OMJPI shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of OMJPI's final Annual Report shall be initiated no later than one year after OMJPI's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify OMJPI of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, OMJPI may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. OMJPI agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with OMJPI prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to OMJPI a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

OMJPI represents that, prior to the Effective Date, it implemented a disclosure program. OMJPI shall maintain a Disclosure Program during the term of the CIA. To the extent not already accomplished, within 90 days after the Effective Date, OMJPI shall modify its Disclosure Program to include a mechanism (a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with OMJPI's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. OMJPI shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-

mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, OMJPI shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an “Ineligible Person” shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>);

and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* OMJPI shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. OMJPI shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. OMJPI shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. OMJPI shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) OMJPI to (if applicable) refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. OMJPI understands that items or services furnished by excluded persons are not payable by Federal health care programs and that OMJPI may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether OMJPI meets the requirements of Section III.F.

3. *Removal Requirement.* If OMJPI has actual notice that a Covered Person has become an Ineligible Person, OMJPI shall remove such Covered Person from responsibility for, or involvement with, OMJPI's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by

Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If OMJPI has actual notice that a Covered Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, OMJPI shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, OMJPI shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to OMJPI conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that OMJPI has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. OMJPI shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Government Reimbursed Products for which penalties or exclusion may be authorized; or
- b. the filing of a bankruptcy petition by OMJPI.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If OMJPI determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, OMJPI shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.H.1.a.* For Reportable Events under Section III.H.1.a, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;
- b. a description of OMJPI's actions taken to correct the Reportable Event; and
- c. any further steps OMJPI plans to take to address the Reportable Event and prevent it from recurring.
- d. OMJPI shall not be required to report as a Reportable Event any matter previously disclosed under section III.G.

4. *Reportable Events under Section III.H.1.b.* For Reportable Events under Section III.H.1.b, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between OMJPI and the FDA that materially discusses OMJPI's or a Covered Person's actual or potential unlawful or improper promotion of OMJPI's products (including any improper dissemination of information about off-label indications), OMJPI shall provide a copy of the report, correspondence, or communication to the OIG. OMJPI shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Internal Monitoring Program.

To the extent not already accomplished, within 120 days after the Effective Date, OMJPI shall establish an Internal Monitoring Program (IMP) to evaluate and monitor various aspects of OMJPI's interactions with HCPs and HCIs, including interactions between sales representatives and HCPs and HCIs. As set forth in more detail below, the IMP shall include three elements: i) Observations of sales force representatives; ii) Records Reviews; and iii) Speaker/Consultant Monitoring Activities.

1. *Observations.* OMJPI compliance personnel and other appropriately trained OMJPI representatives who are not currently working in the marketing or field sales organization shall conduct direct field observations (Observations) of sales force representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with OMJPI's Policies and Procedures. These Observations shall be full day ride-alongs with sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and other representatives of HCIs during the workday. The Observations shall be scheduled throughout the year, randomly selected by OMJPI compliance personnel and other appropriately trained OMJPI representatives as described above, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, OMJPI compliance personnel or the designee shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the OMJPI compliance professional or other appropriately trained OMJPI representative(s);
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with OMJPI policy; and
- 6) the identification of any potential off-label promotional activity by the field sales representative.

OMJPI compliance personnel and other appropriately trained OMJPI representatives who are not currently working in the marketing or field sales organization shall conduct at least 30 full-day Observations during each Reporting Period. The number of inspections conducted for each therapeutic area and product shall be proportional in number to the size of each therapeutic area and product, and shall be conducted across the United States.

In the event that a compliance issue, including but not limited to potential off-label promotion or noncompliance with OMJPI's compliance program or policies and procedures, is identified during any Observation, OMJPI shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. The compliance department shall maintain records of any compliance issues identified during an Observation and any corrective action.

2. *Records Reviews.* OMJPI shall review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance or legal violations. For each Reporting Period, OMJPI shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about OMJPI's products provided by OMJPI no later than 60 days prior to the beginning of the Reporting Period and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed during a given Reporting Period, OMJPI shall select the three products to be reviewed. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

These Records Reviews shall be conducted via a team that relies on appropriate resources and shall include the monitoring and review of selected: 1) records and systems associated with sales representatives' interactions with HCPs and HCIs (including records and systems relating to payments for services made to HCPs or HCIs); 2) records relating to training provided to HCPs; 3) promotional and other materials about the selected Government Reimbursed Products; 4) sales representative call notes; 5) sales representatives' other electronic records; and 6) recorded results of the Observations of sales force representatives and applicable notes or information from the sales representatives' managers.

3. *Speaker/Consultant Monitoring Activities.* To the extent that OMJPI engages or reimburses an HCP to provide services or participate in training about Government Reimbursed Products (e.g., as a speaker, member of an advisory board or as

a participant in data-gathering exercises), such HCPs shall be referred to herein as Consultants. To the extent not already required, OMJPI shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. OMJPI shall continue such requirements during the CIA. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by OMJPI. Prior to the retention of Consultants, OMJPI shall ensure that a business rationale form has been completed to justify the retention of or payment to the Consultant. The business rationale form shall include an identification of the business need for the information to be provided by the Consultant and provide specific details about the consulting arrangement (including, for example, information about the numbers and qualifications of the HCPs to be engaged, the agenda for any proposed advisory board meeting, and a description of the proposed work to be done and type of work product to be generated by the Consultant).

Prior to the Effective Date, with regard to speaker programs, OMJPI required all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of OMJPI approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses.) OMJPI shall continue such requirements during the CIA.

OMJPI shall ensure that all speaker programs continue to be initiated and tracked through a centralized, electronic system that includes controls (including the use of a centrally managed, pre-set rate structure for payment that is determined based on a fair-market value analysis conducted by OMJPI) designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.

OMJPI shall continue to maintain a comprehensive list of speaker program attendees through its centralized system. In addition, OMJPI shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. OMJPI shall require certifications by sales representatives or other OMJPI personnel that a speaker program complied with OMJPI requirements, or in the event of noncompliance, OMJPI shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation. OMJPI shall maintain

the controls around speaker programs as described above throughout the term of the CIA.

To the extent not already accomplished, within 120 days after the Effective Date, OMJPI shall establish a process to develop an annual Consultant budgeting plan that identifies the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Personnel from OMJPI's legal or HCC department shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan.

Within 120 days after the Effective Date, OMJPI shall also establish a process for the review by personnel from OMJPI's legal or HCC department of all business rationale forms associated with the retention of any Consultant prior to the retention of the Consultant. The purpose of this legal/HCC review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and that Consultant arrangements are consistent with the applicable approved Consultant budgeting plan. Any deviations from the Consultant budgeting plans shall be documented in the business rationale form (or elsewhere, as appropriate) and shall be considered as part of the legal/HCC review. To the extent not already accomplished, within 120 days after the Effective Date, OMJPI shall amend its policies to require the collection, assessment, and retention of work product generated by Consultants.

Within 120 days after the Effective Date, to the extent not already accomplished, OMJPI shall establish a Consultant Monitoring Program through which OMJPI or HCC personnel shall conduct audits (Consultant Program Audits) of at least 50 consultant programs with HCPs during each Reporting Period. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a random sampling approach. The Consultant Monitoring Program shall ensure that the Consultant Program Audits review the range of types of consulting activities regularly performed by OMJPI Consultants. Specifically, 40 of the programs to be audited shall be speaker programs and the remaining 10 programs to be audited shall be other types of fee-for-service programs.

Personnel conducting the Consultant Program Audits shall review business rationale forms, consultant contracts, materials relating to the program or work of the Consultant (including a verification that the work product resulting from any Consultant-related program or event or otherwise generated by the Consultant is consistent with the

stated business need set forth on the business rationale form or elsewhere), and other information, in order to assess whether the programs and arrangements were conducted in a manner consistent with OMJPI's Policies and Procedures. In the event that the Consultant activity is a speaker program, the review shall also include a review of slides and other materials used as part of the speaker program, speaker statements made during the program, and OMJPI sales representative activities during the program to assess whether the programs were conducted in a manner consistent with OMJPI's Policies and Procedures.

4. *Reporting and Follow-up.* Personnel conducting the Observations, Records Reviews, and Consultant Program Audits shall have access to all relevant records and information necessary to assess OMJPI's interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the Observations, Records Review, and Consultant Program Audits shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Department for appropriate follow-up activity.

In the event that a compliance issue, including but not limited to a potential off-label promotion or noncompliance with OMJPI's legal requirements, compliance program requirements or Policies and Procedures, is identified during any Observation, Records Review, or Consultant Program Audit, OMJPI shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.H above, as applicable.

OMJPI shall include a summary of the IMP and the results of the IMP as part of each Annual Report. As part of each Annual Report, OMJPI also shall provide the OIG with copies of the Observation report for any instances in which it was determined that a sales representative engaged in improper promotion and a description of the action(s) that OMJPI took as a result of such determinations. OMJPI shall make the Observation reports for all other Observations available to the OIG upon request.

K. Notice to Health Care Providers and Entities.

Within 90 days after the Effective Date, OMJPI shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs upon which OMJPI currently calls. This notice shall be dated and shall be signed by OMJPI's President. The body of the letter shall state the following:

As you may be aware, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and use of one of its products.

This letter provides you with additional information about the settlement, explains OMJPI's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that OMJPI unlawfully promoted the drug Topamax for uses not approved by the Food & Drug Administration (FDA). To resolve these matters, Ortho-McNeil Pharmaceutical, LLC (OMP) pled guilty to a misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act (FDCA), and OMJPI and OMP together agreed to pay \$ 81.5 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[OMJPI shall include a link to the USAO, OCL, and OMJPI websites in the letter.]**

As part of the federal settlement, OMJPI also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, OMJPI agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by OMJPI's representatives to OMJPI's Compliance Department or the Food & Drug Administration (FDA).

Please call OMJPI at **1-800-775-5514** or visit us at **www.omjpi.com** if you have questions about the settlement referenced above or to report any instances in which you believe that an OMJPI representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to **1-800-526-7736**.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, OMJPI shall provide to the OIG a summary of the calls and messages received.

L. Reporting of Physician Payments.

1. *Posting of Payment Information*

Phase I Reporting: By September 30, 2010, OMJPI shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians and Related Entities (as defined below in Section III.L.2) who or which received any Phase I Payments (as defined below in Section III.L.2) directly or indirectly from OMJPI during the first two calendar quarters of 2010.

After the initial posting, 60 days after the end of each subsequent calendar quarter, OMJPI shall also post on its website a listing of updated information about all Phase I Payments made during the preceding calendar quarter. No later than May 1, 2011, OMJPI shall also post on its website a report of the cumulative value of Phase I Payments provided to each physician and/or Related Entity during the preceding calendar year.

Phase II Reporting: By July 1, 2011, OMJPI shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians and Related entities who or which received any Phase II Payments (as defined below in Section III.L.2) directly or indirectly from OMJPI during the first calendar quarter of 2011 and the aggregate value of such Payments. Thereafter, 60 days following the end of

each calendar quarter, OMJPI shall also post on its website a listing of updated information about all Phase II Payments made during the preceding calendar quarter and the aggregate value of such Payments. No later than May 1, 2012, OMJPI shall also post on its website a report of the cumulative value of Phase II Payments provided to each physician and/or Related Entity during the preceding calendar year. The commencement of the Phase II reporting will terminate the obligations of Phase I reporting.

Phase III Reporting: Beginning on the earlier of June 30, 2012 or 180 days from the publication by HHS of final regulations implementing the Patient Protection and Affordable Care Act (Public Law 111-148) (the “Act”), OMJPI shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians and Related entities who or which received Phase III Payments (as defined below in Section III.L.2) directly or indirectly from OMJPI during the first calendar quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days following the end of each calendar quarter, OMJPI shall also post on its website a listing of updated information about all Phase III Payments made during the preceding calendar quarter and the aggregate value of such Payments. OMJPI shall continue to post such information on its website on a quarterly basis throughout the term of the CIA.

No later than May 1, 2013, OMJPI shall also post on its website a report of the cumulative value of Phase III Payments provided to each physician and/or Related Entity during the preceding calendar year. Thereafter, on or before May 1 of each subsequent year, OMJPI shall post a report on the cumulative value of Payments provided to each physician and/or Related Entity during the preceding calendar year. The commencement of Phase III reporting will terminate the obligations of Phase II reporting.

For all website postings, each listing shall include a complete list of all individual physicians and Related Entities to whom or to which OMJPI directly or indirectly made Payments in the preceding calendar quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians’ last name or the name of the Related Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (*e.g.*, \$0 - \$10,000; \$10,001- \$20,000; *etc.*) or in the actual amount paid, provided, however, that the Payment amounts shall be listed in the same way (incrementally or in actual amounts) for all physicians and/or Related Entities on the listing. For each physician, the applicable listing shall include the following information: i) physician’s full name; ii) name of Related Entity (if applicable); iii) city and state of the physician’s practice or the Related Entity; iv) the purpose of the payment(s); and (v) the aggregate value of the

payment(s) in the preceding quarter(s) or year (as applicable). Each quarterly and annual listing shall be easily accessible and readily searchable.

2. Definitions and Miscellaneous Provisions

OMJPI shall continue to make each annual listing and the most recent quarterly listing of Payment information available on its website at least throughout the term of this CIA. OMJPI shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.L affects the responsibility of OMJPI to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

For purposes of this Section III.L, the term “Phase I Payments” is defined to include all payments or transfers of value (whether in cash or in kind) made by OMJPI to physicians and/or to Related Entities in return for contracted services for OMJPI to be performed expressly by the physician. The term Phase I Payments is defined as payments, fees, and honoraria, or compensation for, or in connection with services (such as consulting, speaking, advisory board) rendered; as well as payments or reimbursement for entertainment, gifts, trips or travel; or other economic benefit furnished or reimbursed by OMJPI in connection with contracted services (and which are not otherwise covered or paid for by the Physician or Related Entity). The term also includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom OMJPI would otherwise report a Payment if made directly to the physician.

For purposes of this Section III.L, the term “Phase II Payments” includes all Phase I Payments (as defined above) in addition to all payments or transfers of value made by OMJPI for research, education, and payment or reimbursement by OMJPI for business meals, as well as for all Phase I Payments, irrespective of the contract status of the physicians or Related Entity.

For purposes of this Section III.L, the term “Phase III Payments” includes all Phase I and Phase II Payments (as defined above) in addition to all other payments or transfers of value made by OMJPI, directly or indirectly, to a physician or Related Entity.

For purposes of its website posting of the quarterly and annual listings of Payments, and with regard only to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Act, OMJPI may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

For purposes of this Section III.L, the term “Payment” as used in the definition of Phase I Payments, Phase II Payments, and Phase III Payments does not include transfers of anything of value or other items that are not included in the definition of “Payment” or are excluded from the definition of “Payment” by § 1128G(e)(1) under Section 6002 of the Act and any subsequent regulations promulgated thereunder.

For purposes of this Section III.L, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, OMJPI changes locations or closes a business unit or location related to Promotional and Product Services Related Functions, OMJPI shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, OMJPI purchases or establishes a new business unit or location related to Promotional and Product Services Related Functions, OMJPI shall notify OIG no later than the date that the purchase or establishment is publicly disclosed. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, OMJPI proposes to sell any or all of its business units or locations that are subject to this CIA, OMJPI shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. This notification shall include a description of the business unit or location to

be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, OMJPI shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of OMJPI's Code of Conduct required by Section III.B.1;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to the OIG upon request);
8. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all

existing agreements with parties employing Third-Party Personnel; and (c) a description of the entities' response to OMJPI's letter;

9. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between OMJPI and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to OMJPI;

12. a description of the Disclosure Program required by Section III.E;

13. a description of the process by which OMJPI fulfills the requirements of Section III.F regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;

15. a certification by the Compliance Officer that the notice required by Section III.K was mailed to each HCP and HCI, the number of HCPs and HCIs that received a copy of the notice, a sample copy of the notice required by Section III.K, and a summary of the calls or messages received in response to the notice;

16. (if applicable) a certification from the Compliance Officer that information regarding all Payments has been posted on OMJPI's website as required by Section III.L;

17. a list of all of OMJPI's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which OMJPI currently submits claims (if applicable);

18. a description of OMJPI's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

B. Annual Reports. OMJPI shall submit to OIG annually a report with respect to the status of, and findings regarding, OMJPI's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4, and a copy of the Compliance Program Review Report described in Section III.A.3;

2. a copy of the Board of Directors' resolution required by Section III.A.3;

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have

completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

5. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing agreements with parties employing Third-Party Personnel; and (c) a description of the entities' response to OMJPI's letter;

6. the following information regarding each type of training required by Section III.C:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

8. OMJPI's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

9. a summary and description of any and all current and prior engagements and agreements between OMJPI and the IRO, if different from what was submitted as part of the Implementation Report;

10. a certification from the IRO regarding its professional independence and objectivity with respect to OMJPI;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or Government Reimbursed Products;

12. any changes to the process by which OMJPI fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by OMJPI in response to the screening and removal obligations set forth in Section III.F;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

16. a summary describing any communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

17. all information required by Section III.J relating to the Internal Monitoring Program;

18. a summary of the calls and messages received in response to the notice required by Section III.K and the disposition of those calls and messages;

19. a certification from the Compliance Officer that information regarding all Payments has been posted on OMJPI's website as required by Section III.L;

20. a description of all changes to the most recently provided list of OMJPI's locations (including addresses) as required by Section V.A.17; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which OMJPI currently submits claims (if applicable); and

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The following certifications shall be included in the Implementation Report and Annual Reports:

1. Certifying Employees: In each Annual Report, OMJPI shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Compliance Officer: In each Implementation Report and Annual Report, OMJPI shall include the following individual certification by the Compliance Officer:

a. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, OMJPI is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, OMJPI has complied with its obligations under the Settlement Agreement: 1) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; 2) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and 3) to identify and adjust any past charges or claims for unallowable costs;

d. OMJPI's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, OMJPI's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside OMJPI have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in

accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by OMJPI and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. OMJPI's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.f) and, for each product the call plans were found to be consistent with OMJPI's policy objectives as referenced above in Section III.B.3.f.

D. Designation of Information. OMJPI shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. OMJPI shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch
 Office of Counsel to the Inspector General
 Office of Inspector General
 U.S. Department of Health and Human Services
 Cohen Building, Room 5527
 330 Independence Avenue, S.W.
 Washington, DC 20201
 Telephone: 202.619.2078
 Facsimile: 202.205.0604

OMJPI: Kris Curry
Compliance Officer
Ortho-McNeil-Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560
Telephone: 609.730.4397
Facsimile: 609.730.2077

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, OMJPI may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of OMJPI's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of OMJPI's locations for the purpose of verifying and evaluating: (a) OMJPI's compliance with the terms of this CIA; and (b) OMJPI's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by OMJPI to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of OMJPI's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. OMJPI shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. OMJPI's employees may elect to be interviewed with or without a representative of OMJPI present.

VIII. DOCUMENT AND RECORD RETENTION

OMJPI shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify OMJPI prior to any release by OIG of information submitted by OMJPI pursuant to its obligations under this CIA and identified upon submission by OMJPI as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, OMJPI shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

OMJPI is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, OMJPI and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OMJPI fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a resolution from the Board of Directors;
- d. a written Code of Conduct;
- e. written Policies and Procedures;

- f. the training of Covered Persons and Relevant Covered Persons;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. reporting of Reportable Events;
- k. notification of communications with FDA;
- l. an Internal Monitoring Program;
- m. notification to HCPs and HCIs as required by Section III.K; and
- n. posting of any Payments as required by Section III.L.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OMJPI fails to engage an IRO, as required in Section III.D and Appendices A-B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OMJPI fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OMJPI fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

5. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day OMJPI employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, OMJPI's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or

otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which OMJPI can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

6. A Stipulated Penalty of \$1,500 for each day OMJPI fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date OMJPI fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of OMJPI as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$1,000 for each day OMJPI fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to OMJPI, stating the specific grounds for its determination that OMJPI has failed to comply fully and adequately with the CIA obligation(s) at issue and steps OMJPI shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after OMJPI receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions. OMJPI may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after OMJPI fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after OMJPI receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that OMJPI has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify OMJPI of: (a) OMJPI's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, OMJPI shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event OMJPI elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until OMJPI cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that OMJPI has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by OMJPI to report a Reportable Event and take corrective action, as required in Section III.H;

- c. a failure to engage and use an IRO in accordance with Section III.D and Appendix B;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by OMJPI constitutes an independent basis for OMJPI's exclusion from participation in the Federal health care programs. Upon a determination by OIG that OMJPI has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify OMJPI of: (a) OMJPI's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude".)

3. *Opportunity to Cure.* OMJPI shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. OMJPI is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) OMJPI has begun to take action to cure the material breach; (ii) OMJPI is pursuing such action with due diligence; and (iii) OMJPI has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, OMJPI fails to satisfy the requirements of Section X.D.3, OIG may exclude OMJPI from participation in the Federal health care programs. OIG shall notify OMJPI in writing of its determination to exclude OMJPI (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below,

the exclusion shall go into effect 30 days after the date of OMJPI's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, OMJPI may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights.* Upon OIG's delivery to OMJPI of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, OMJPI shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether OMJPI was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. OMJPI shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders OMJPI to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless OMJPI requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a

proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether OMJPI was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) OMJPI had begun to take action to cure the material breach within that period; (ii) OMJPI has pursued and is pursuing such action with due diligence; and (iii) OMJPI provided to OIG within that period a reasonable timetable for curing the material breach and OMJPI has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for OMJPI, only after a DAB decision in favor of OIG. OMJPI's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude OMJPI upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that OMJPI may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. OMJPI shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of OMJPI, OMJPI shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

OMJPI and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of OMJPI;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. The undersigned OMJPI signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.

/Michelle R. Ryan/

Michelle R. Ryan
Officer
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

4/27/2010
Date

/Kris L. Curry/

Kris L. Curry
Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Compliance Officer

4/27/2010
Date

Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen
Pharmaceuticals, Inc.

Date

Seth H. Lundy
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen
Pharmaceuticals, Inc.

Date

Corporate Integrity Agreement
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

ON BEHALF OF ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.

Michelle R. Ryan
Officer
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Date

Kris L. Curry
Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Compliance Officer

Date

/Mark A. Jensen/

4/27/2010

Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen
Pharmaceuticals, Inc.

Date

/Seth H. Lundy/

4/27/2010

Seth H. Lundy
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen
Pharmaceuticals, Inc.

Date

Corporate Integrity Agreement
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Gregory E. Demske/

4/28/10

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

Date

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

OMJPI shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify OMJPI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, OMJPI may continue to engage the IRO.

If OMJPI engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, OMJPI shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify OMJPI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, OMJPI may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Government Reimbursed Products are reimbursed;
2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and OMJPI.

E. IRO Removal/Termination.

1. *OMJPI Termination of IRO.* If OMJPI terminates its IRO during the course of the engagement, OMJPI must submit a notice explaining its reasons to OIG no later than 30 days after termination. OMJPI must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require OMJPI to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring OMJPI to engage a new IRO, OIG shall notify OMJPI of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, OMJPI may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence, or performance of

its responsibilities and to present additional information regarding these matters. OMJPI shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with OMJPI prior to requiring OMJPI to terminate the IRO. However, the final determination as to whether or not to require OMJPI to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA Promotional and Product Services Review

I. Promotional and Product Services Review, General Description

As specified more fully below, OMJPI shall retain an Independent Review Organization (IRO) to perform reviews to assist OMJPI in assessing and evaluating its systems, processes, policies, procedures, and practices related to OMJPI's Promotional and Product Services Related Functions (IRO Review). The IRO Review shall consist of two components - a systems review (the "Promotional and Product Services Systems Review" or "Systems Review"), and a transactions review (the "Promotional and Product Services Transactions Review" or "Transactions Review") as described more fully below. OMJPI may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in OMJPI's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If OMJPI materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of OMJPI's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Services Related Functions. Where practical, OMJPI personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by OMJPI pursuant to the preceding sentence.

Specifically, the IRO shall review OMJPI's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) OMJPI's systems, policies, processes, and procedures applicable to the manner in which OMJPI representatives (including sales representatives and/or Medical Information & Services department personnel) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses Government Reimbursed Products) and the dissemination of materials relating to off-label uses of products. This review includes:
 - a) the manner in which OMJPI sales representatives and marketing personnel handle requests for information about off-label uses of Government Reimbursed Products (*e.g.*, by referring all such requests to Medical Information & Services personnel at OMJPI);
 - b) the manner in which Medical Information and Services department personnel, including those at OMJPI's headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
 - c) the form and content of information and materials related to Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by OMJPI;
 - d) OMJPI's systems, processes, and procedures (including the Inquiries Database) to track requests for information about off-label uses of products and responses to those requests;
 - e) the manner in which OMJPI collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database;
 - f) the processes and procedures by which the Compliance Officer (and other appropriate individuals within OMJPI) identify situations in which it appears that off-label or other improper promotion may have occurred; and
 - g) OMJPI's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

2) OMJPI's policies and procedures applicable to the manner and circumstances under which its Medical Information & Services department personnel (including any medical science liaisons or analogous personnel) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the medical personnel at such meetings or events;

3) OMJPI's systems, policies, processes, and procedures relating to OMJPI's internal review and approval of information and materials related to Government Reimbursed Products disseminated to HCPs or HCIs by OMJPI;

4) OMJPI's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that OMJPI establishes different methods of compensation for different products, the IRO shall review each type of compensation arrangement separately;

5) OMJPI's systems, processes, policies, and procedures relating to the development and review of call plans for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6) OMJPI's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution Plans for Government Reimbursed Products. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from OMJPI (including, separately, from OMJPI sales representatives and OMJPI's Medical Information & Services department); and

7) OMJPI's systems, processes, policies, and procedures relating to consultant, speaker, or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships, and ad hoc

advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of OMJPI's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-7 above, including a general description of OMJPI's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-7 above are made known or disseminated within OMJPI;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);
- 5) a detailed description of OMJPI's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that OMJPI may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in OMJPI's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. IRO Transaction Review

As described more fully below in Sections III.A-E, the Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of OMJPI's call plans and OMJPI's call plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by OMJPI pursuant to Section III.L of the CIA; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.e of the CIA, OMJPI shall establish a database to track information relating to requests for information received by OMJPI about its Government Reimbursed Products (hereafter "Inquiries"). Specifically, OMJPI shall document and record all Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in a database (the "Inquiries Database"). OMJPI shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from OMJPI (including a record of any materials provided in response to the request); and 7) the name of the OMJPI representative who called upon or interacted with the HCP or HCI. In addition, HCC will record the date and name of the individual at HCC who reviewed the Inquiry, if applicable.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("Inquiry Report"). The Compliance Officer shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer, in consultation with other appropriate OMJPI personnel, suspects that improper off-label promotion

may have occurred in connection with any Inquiry, the Compliance Officer shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty (40) of the Inquiries reviewed by the IRO shall be Inquiries for which OMJPI conducted an Off-Label Review, and the other 10 shall be Inquiries for which OMJPI did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by OMJPI based on the Off-Label Review findings.

B. IRO Review of OMJPI's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of OMJPI's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.f of the CIA. OMJPI shall provide the IRO with: i) a list of Government Reimbursed Products promoted by OMJPI during the Reporting Period; ii) information about the FDA-approved uses for each OMJPI product; and iii) the call plans for each product. OMJPI shall also provide the IRO with information about the reviews of call plans that OMJPI conducted during the Reporting Period and any modifications to the call plans made as a result of OMJPI's reviews.

For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by OMJPI in conducting its review and/or modification of the call plan in order to determine whether OMJPI followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call plan are inconsistent with OMJPI's criteria relating to the call plan and/or OMJPI's Policies and Procedures. The IRO shall also note any instances in which it appears that OMJPI failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of OMJPI Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. OMJPI shall provide the IRO with: i) a list of products for which OMJPI distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each OMJPI product; and iii) information about OMJPI's policies and procedures relating to the distribution of samples of each type of product, including OMJPI's Sample Distribution Plan showing which type samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. OMJPI shall also provide the IRO with information about the reviews of Sample Distribution Plans that OMJPI conducted during the Reporting Period as set forth in Section III.B.3.g of the CIA and any modifications to the distribution plans made as a result of OMJPI's reviews.

For each product for which OMJPI distributed samples during the Reporting Period, the IRO shall randomly select a sample of 30 separate instances in which OMJPI provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the OMJPI product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual OMJPI sales representative or department (e.g., Medical Information & Services) provided the sample to the HCP or HCI; 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter or call to Medical Information & Services department); and 5) the manner and mechanism through which the request was fulfilled (e.g., sales representative distribution or direct shipment).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the product approved by the FDA and whether the sample was distributed by a OMJPI representative in a manner consistent with OMJPI's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by an OMJPI representative other than a sales representative,

the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a OMJPI sales representative, conversation with a representative of OMJPI's Medical Information & Services department, independent research or knowledge of the HCP or HCI, *etc.*)

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. For each such situation, the IRO shall note the process followed by OMJPI in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that OMJPI failed to follow its Sample Distribution Plan for the product(s) provided during the Sampling Event.

D. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

As set forth in Section III.L of the CIA, OMJPI shall initially post quarterly by September 30, 2010 and, beginning on May 1, 2011, annual listings of physicians and Related Entities who received Payments, as defined in the CIA, directly or indirectly from OMJPI during the prior calendar year or quarter as applicable. For purposes of the IRO review as set forth in this Section III.D, each annual listing shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; iv) the purpose of the payment(s); and (v) the aggregate value of the Payment(s) in the preceding year.

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters

personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in OMJPI's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that OMJPI's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with OMJPI's policies.)

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that OMJPI otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or

- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with OMJPI's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but OMJPI has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that OMJPI otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

E. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify OMJPI of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or OMJPI shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review

conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in OMJPI's systems, processes, policies, and procedures based on its review of each Additional Item.)

OMJPI may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow OMJPI's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of OMJPI's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and OMJPI's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies OMJPI's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, OMJPI shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of OMJPI's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by OMJPI in its internal audits.

F. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
 - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by OMJPI as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in OMJPI's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in OMJPI's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by OMJPI during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each OMJPI product: i) a description of the criteria used by OMJPI in developing or reviewing the call plans and for including or

excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by OMJPI of the call plans and an indication of whether OMJPI reviewed the call plans as required by Section III.B.3.f of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with OMJPI's criteria relating to the call plan and/or OMJPI's Policies and Procedures; and iv) a description of all instances in which it appears that OMJPI failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;

- h) the findings and supporting rationale regarding any weaknesses in OMJPI's systems, processes, policies, procedures, and practices relating to OMJPI's call plans or the review of the call plans, if any;
- i) recommendations, if any, for changes in OMJPI's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

- j) for each OMJPI Government Reimbursed Product distributed during the Reporting Period: i) a description of Sample Distribution Plan (including whether sales representatives may provide samples of the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by OMJPI in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that OMJPI failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in OMJPI's systems, processes, policies, procedures, and practices relating to OMJPI's distribution of samples of OMJPI Government Reimbursed Products, if any;

- l) recommendations, if any, for changes in OMJPI's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: i) all required Control Documents exist; ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable OMJPI policy; iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; iv) each Control Document reflects that OMJPI's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and v) any disciplinary action that was undertaken in those instances in which OMJPI policies were not followed;
- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- q) for each Additional Item reviewed, a description of the review conducted;

- r) for each Additional Item reviewed, the IRO's findings based on its review;
- s) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in OMJPI's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- t) for each Additional Item reviewed, recommendations, if any, for changes in OMJPI's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.